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L5: Entry 2 of 2 File: USPT Sep 22, 1998

DOCUMENT-IDENTIFIER: US 5811388 A
TITLE: Delivery of drugs to the lower GI tract

Brief Summary Text (56):
The particle size of the drug used in preparing the compositions of this invention may vary in size from about a tenth micron in size to more than 300 microns. It may also offer certain advantages to prepare microspheres (e.g. nanospheres or nanocapsules) of the peptides to aid in stabilizing and handling such compounds. For example, polyalkylcyanoacrylate nanocapsules with an average size of 220 nanometers (NM) may be prepared according to the method of Al Kouri, et al., Int. J. Pharm. 28:125432, 1986.

Brief Summary Text (74):
The most extensively used polymer is cellulose acetate phthalate (CAP) which is capable of functioning effectively as an enteric coating. However, a pH greater than 6 usually is required for solubility and thus a delay in drug release may ensue. It also is relatively permeable to moisture and gastric fluid compared to most enteric polymers. Thus it is susceptible to hydrolytic decomposition where phthalic and acetic acids are split off, resulting in a change in polymeric, and therefore enteric, properties. Another useful polymer is polyvinyl acetate phthalate (PVAP) which is less permeable to moisture and gastric fluid, more stable to hydrolysis and able to ionize at a lower pH, resulting in earlier release of actives in the duodenum. A more recently available polymer is hydroxypropyl methylcellulose phthalate. This has similar stability to PVAP and dissociates in the same pH range. A final example of currently used polymers are those based on methacrylic acid--methacrylic acid ester copolymers with acidic ionizable groups. These are represented by polymers having the tradename Eudragit available through Rohm Pharma. They have been reported to suffer from the disadvantage of having delayed breakdown even at relatively high pH.

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L6: Entry 18 of 18 File: DWPI Feb 14, 1991

DERWENT-ACC-NO: 1991-090638
DERWENT-WEEK: 199113

TITLE: Oral compsn. for treatment of ulcerous colitis and crohn's disease - contains 5-amino:salicylic acid or sal:azo:sulpha:pyridine

PATENT-ASSIGNEE: TEIKOKU SEIYAKU KK (TEIKN)

PRIORITY-DATA: 1989JP-0167694 (June 29, 1989)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
JP 03034929 A	February 14, 1991		000	

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
JP 03034929A	June 29, 1989	1989JP-0167694	

INT-CL (IPC): A61K 9/16; A61K 31/60; A61K 47/36

ABSTRACTED-PUB-NO: JP 03034929A
BASIC-ABSTRACT:

Oral compsn. for the treatment of ulcerous colitis and Crohn's disease contains 5-aminosalicylic acid, salazosulpha-pyridine, or their pharmacologically acceptable salts as an active ingredient, together with water-insoluble potassium alginate obtd. by mixing alginic acid or the salt with potassium salt as a binder. This compsn. is pref. coated with an enteric polymer.

Enteric polymer includes hydroxypropyl methylcellulose phthalate (HPMC), hydroxypropyl methylcellulose acetate succinate (HPMCAS), shellac, Eudragit, cellulose acetate phthalate (CAP), or the mixt., in an amt. of 0.1-3 pts. wt. of the compsn. Potassium salt is pref. potassium chloride, in an amt. of 50-90 wt%.

Pref. compsn. contains 1-30 wt% alginic acid.

ADVANTAGE - This prepn. can efficiently release a drug at target sites, i.e., the lower part of small intestine or colon. This may be granules or fine granules.

ABSTRACTED-PUB-NO: JP 03034929A
EQUIVALENT-ABSTRACTS:

CHOSEN-DRAWING: Dwg.0/0

DERWENT-CLASS: A96 B03 B05
CPI-CODES: A10-E21A; A12-B; A12-V01; B04-B04M; B04-C02A; B04-C02D; B07-D04C; B10-B02E; B12-D07; B12-E08; B12-M11D;

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L6: Entry 17 of 18 File: USPT Nov 21, 1995

DOCUMENT-IDENTIFIER: US 5468503 A
TITLE: Oral pharmaceutical preparation released at infragastrointestinal tract

Detailed Description Text (7):
An enteric coating is formed on the surface of the hard capsule. That is, by forming the coating on the surface of the hard capsule, the hard capsule can pass through stomach while the degradation thereof is prevented. The enteric compound as the raw material of such coating includes, for example, methacrylate copolymer (Eudragit L and Eudragit S; all as product names), hydroxypropyl methyl cellulose phthalate (HPMCP), hydroxypropyl methyl cellulose acetate succinate (HPMCAS), cellulose acetate phthalate (CAP), hydroxypropyl methyl cellulose (HPMC), shellac and the like.

L4: Entry 59 of 65 File: USPT Jul 29, 1997

US-PAT-NO: 5651983
DOCUMENT-IDENTIFIER: US 5651983 A

TITLE: Bisacodyl dosage form for colonic delivery

DATE-ISSUED: July 29, 1997

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Kelm; Gary Robert	Cincinnati	OH		
Manring; Gary Lee	Hamilton	OH		
Davis; Paula Denise	Cincinnati	OH		
Dobrozsi; Douglas Joseph	Loveland	OH		
Mandel; Kenneth Gary	Fairfield	OH		
McCauley-Meyers; David Lee	Middletown	OH		

US-CL-CURRENT: 424/452; 424/464, 424/465, 424/468, 514/58, 514/777, 514/778

CLAIMS:

What is claimed is:

1. A pharmaceutical composition in a unit dosage form for peroral administration in a human or lower animal, having a gastrointestinal tract comprising a small intestine and a colon with a lumen therethrough having an inlet to the colon from the small intestine, comprising:

a. a safe and effective amount of rapidly dissolving bisacodyl incorporated into or coated on the surface of a dosage form selected from the group consisting of a spherical substrate, an elliptical substrate, a hard capsule, or a compressed tablet, with a maximum diameter of about 3 mm to about 10 mm; and

b. an enteric polymer coating material;

wherein the dosage form has a smooth surface free from edges or sharp curves; the elliptical substrate and the hard capsule have a ratio of the long to short diameters of no greater than about 1.5; the rapidly dissolving bisacodyl is released at a point near the inlet to, or within the colon; the enteric polymer coating material begins to dissolve in an aqueous media at a pH between about 5 to about 6.3; and the enteric polymer coating material has a coating thickness of at least about 250 .mu.m.

2. The composition of claim 1 wherein the rapidly dissolving bisacodyl is selected from the group consisting of micronized bisacodyl, an inclusion complex of bisacodyl and a cyclodextrin, a solid dispersion of bisacodyl on a hydrophilic substrate, commercially available bisacodyl powder, and one of the

preceding solid forms of bisacodyl suspended in a self-emulsifying lipid vehicle, the vehicle being a liquid at 37.degree. C. and one in which bisacodyl is not soluble.

3. The composition of claim 2 wherein the rapidly dissolving bisacodyl also comprises a pharmaceutically acceptable excipient selected from the group consisting of diluents, binders, lubricants, disintegrants, glidants, buffers, and mixtures thereof, to enhance the dissolution rate of bisacodyl by promoting disintegration into primary drug particles to maximize surface area.

4. The composition of claim 2 wherein the rapidly dissolving bisacodyl is micronized bisacodyl.

5. The compositon of claim 1 wherein the dosage form is selected from the group consisting of a soft elastic gelatin capsule; a molded spherical substrate or elliptical substrate made from any pharmaceutically acceptable excipient that can be melted or molded; and a spherical substrate or elliptical substrate prepared by coating or layering a substrate onto a seed crystal made of any inert pharmaceutically acceptable excipient.

6. The composition of claim 5 wherein the dosage form is a soft elastic gelatin capsule or a sugar sphere.

7. The composition of claim 1 wherein the enteric polymer coating material is selected from the group consisting of cellulose acetate phthalate, cellulose acetate trimelliate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, poly (methacrylic acid, methyl methacrylate) 1:1, poly(methacrylic acid, ethyl acrylate) 1:1, and compatable mixtures thereof.

8. The composition of claim 7 wherein the enteric polymer coating material is cellulose acetate phthalate.

9. The composition of claim 8 wherein the enteric polymer coating material is plasticized.

10. A pharmaceutical composition in a unit dosage form for peroral administration in a human or lower animal, having a gastrointestinal tract comprising a small intestine and a colon with a lumen therethrough having an inlet to the colon from the small intestine, comprising:

a. a safe and effective amount of micronized bisacodyl incorporated into a soft elastic gelatin capsule with a maximum diameter of about 3 mm to about 10 mm;

b. cellulose acetate phthalate enteric polymer coating material;

wherein the soft elastic gelatin capsule has a smooth surface free from edges or sharp curves; the micronized bisacodyl is released to a point near the inlet to, or within the colon; and the cellulose acetate phthalate has a coating thickness of at least about 250 .mu.m.

11. The composition of claim 10 wherein the cellulose acetate phthalate is plasticized.

12. The composition of claim 10 wherein the micronized bisacodyl has a particle size distribution such that greater than 90% of the particles are

less than 10 .mu.m in effective diameter.

13. The composition of claim 12 wherein the micronized bisacodyl has a particle size distribution such that greater than 95% of the particles are less than 10 .mu.m in effective diameter.

14. The composition of claim 13 wherein the micronized bisacodyl is dispersed into a self-emulsifying lipid vehicle, the vehicle being a liquid at 37.degree. C. and one in which bisacodyl is not soluble.

15. The composition of claim 10 wherein the diameter of the soft elastic gelatin capsule is from about 4 mm to about 7 mm.

16. The composition of claim 15 wherein the cellulose acetate phthalate has a coating thickness of about 350 .mu.m to about 1000 .mu.m when the diameter is about 4 mm.

17. The composition of claim 15 wherein the cellulose acetate phthalate has a coating thickness of about 250 .mu.m to about 800 .mu.m when the diameter is about 7 mm.

18. A pharmaceutical composition in a unit dosage form for peroral administration in a human or lower animal, having a gastrointestinal tract comprising a small intestine and a colon with a lumen therethrough having an inlet to the colon from the small intestine, comprising:

a. a safe and effective amount of micronized bisacodyl coated on the surface of a sugar spherical substrate with a maximum diameter of about 3 mm to about 10 mm;

b. cellulose acetate phthalate enteric polymer coating material; and

c. a barrier coating which coats the sugar spherical substrate prior to coating with cellulose acetate phthalate enteric polymer coating material;

wherein the sugar spherical substrate has a smooth surface free from edges or sharp curves; the micronized bisacodyl is released to a point near the inlet to, or within the colon; and the cellulose acetate phthalate has a coating thickness of at least about 250 .mu.m.

19. The composition of claim 18 wherein the cellulose acetate phthalate is plasticized.

20. The composition of claim 18 wherein the micronized bisacodyl has a particle size distribution such that greater than 90% of the particles are less than 10 .mu.m in effective diameter.

21. The composition of claim 18 wherein the micronized bisacodyl has a particle size distribution such that greater than 95% of the particles are less than 10 .mu.m in effective diameter.

22. The composition of claim 18 wherein substantially all of the sugar spherical substrates have a diameter within about 5% of the mean diameter.

23. The composition of claim 22 wherein the diameter of the sugar spherical substrate is from about 4 mm to about 7 mm.

24. The composition of claim 23 wherein the cellulose acetate phthalate has a coating thickness of about 350 .mu.m to about 1000 .mu.m when the diameter is about 4 mm.

25. The composition of claim 23 wherein the cellulose acetate phthalate has a coating thickness of about 250 .mu.m to about 800 .mu.m when the diameter is about 7 mm.

26. The composition of claim 18 wherein the barrier coating is hydroxypropyl methylcellulose.

27. A method for providing laxation in the colon of a human or lower animal by administering a safe and effective amount of the composition of claim 1 perorally.

28. A method for providing laxation in the colon of a human or lower animal by administering a safe and effective amount of the composition of claim 10 perorally.

29. A method for providing laxation in the colon of a human or lower animal by administering a safe and effective amount of the composition of claim 18 perorally.

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